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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/003.021

11/14/2001

Joseph Manuel Fernandez

INVITI 140-3

2174

7590

08/01/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/003,021

Applicant(s)

FERNANDEZ ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 41-43 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-43 and 45-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. Claims 41-43 and 45-58 are pending and under consideration in this Office Action.
2. The rejection of claims 41-43 and 45-58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' arguments filed 04/18/2006.

### *Claim Rejections - 35 U.S.C. § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 41-43 and 45-58 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dubensky, Jr. et al. (US Patent 6,342,372; reference of record) in view Guan et al. (EP0286239; reference of record) and Gregoire et al. (J Biol Chem. 1996 Dec 20;271(51):32951-9; reference of record).

The teachings of each of the references have been stated in the previous Office Action and are reproduced below.

Applicants' arguments filed 04/18/2006 have been fully considered but they are not persuasive. Applicants' position is that the Dubensky, Jr. et al. reference teaches away from the claimed invention and that the references of Guen et al. or Gregoire et al. may not be used to cure this defect. The examiner respectfully disagrees for the reasons of record as supplemented below.

MPEP 706.02(j) states the following:

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or

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to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Dubensky, Jr. et al. as stated in the previous Office Action teach an oligonucleotide primer comprising the CACC sequence (SEQ ID No. 69) linked to the 5'start codon ATG of nucleic acids encoding heterologous polypeptides, where the sequences surrounding the ATG start codon from base -9 to +1 that conform to the Kozak consensus sequence for efficient translational initiation (see entire publication, especially column 90, lines 46-58). Dubensky, Jr. et al. teach eukaryotic expression vectors that contain the above described nucleic acid have promoters, enhances, selection marker sequence, and origin of replication (see entire patent, especially Figures 8, 11, and 15; and column 2, line 63 to column 50, line 55).

Guan et al. teach expression vectors, prokaryotic and eukaryotic host cells, and methods for making, expressing, isolating, and purifying any protein fused to the *E.coli* maltose binding protein (MBP); that these methods and products are useful for purifying virtually any hybrid polypeptide molecule employing recombinant techniques; and that DNA fragments coding for the target protein and MBP are linked with DNA segment coding for a peptide which is recognized and cut by a proteolytic enzyme for purposes of purifying the protein itself (see entire publication).

Gregoire et al. teach a recombinant protein with a polyhistidine tail which was purified by immobilized metal affinity chromatography (see entire publication).

The rejection of the claims does not solely rest on the teachings and suggestions of Dubensky, Jr. et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polynucleotide comprising the CACC sequence (SEQ ID No. 69) linked to the 5'start codon ATG of nucleic acids encoding heterologous polypeptides taught by Dubensky, Jr. et al. such that the DNA encoding the MBP and DNA encoding a peptide that can be recognized and cut by a protease as taught by Guan et al. is linked to the polynucleotide taught by Dubensky, Jr. et al. Alternatively, the polynucleotide taught by Dubensky, Jr. et al. is modified to have a DNA encoding a polyhistidine tail as taught by Gregoire et al.

The modified-vector of Dubensky, Jr. et al. would have the 5'-CACC sequence, a start codon, an open reading frame, and a nucleic acid sequence encoding a heterologous polypeptide. Thus, the combination of the references of Dubensky, Jr. et al., Guan et al., and Gregoire et al.

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teaches or suggests all the limitations of the claims.

The examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

### *Conclusion*

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**